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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,122	07/31/2003	Rolland F. Hebert		3947

29133 7590 09/30/2004  
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EXAMINER

HENRY, MICHAEL C

ART UNIT PAPER NUMBER

1623

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/631,122	<b>Applicant(s)</b> HEBERT, ROLLAND F.	
	<b>Examiner</b> Michael C. Henry	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

Claims 1-14 are pending in application

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

A written description analysis involves three principle factors:

(1) field of the invention

(2) breath of the claims, and

(3) possession of the claimed invention at the time of filing for each claimed species/genus based upon the teachings of the specification and the field of the invention.

The Federal Circuit court stated that written description of an invention "requires a precise definition, such as by structure, formula, or chemical name, of the claimed subject matter sufficient to distinguish it from other material". *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed Cir. 1997). The court also stated "Naming a type of material generally known to exist, in the absence as to what the material consists of is not a definition of that material". *Id.* Further, the court stated that to adequately describe a claimed genus, adequate

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must describe a representative number of species of the claimed genus, and that one skilled in the art should be able to "visualize or recognize the identity of the members of the genus". Id .

(A) Provide a brief backdrop of the field of the invention. A reference from the BACKGROUND might very well be sufficient.

(B) Outline the scope and content of the claims briefly

(C) At the time of filing, from the disclosure, does it appear applicants were indeed in possession of the claimed invention?

The claims are drawn to a method for preventing diseases or other conditions where free radicals and/or oxidative stress contribute to the pathogenesis, comprising: administering to mammal in need of such treatment an amount of a composition ..... effective for the prevention of diseases and condition including Parkinson's Disease, Alzheimer disease, diabetes, Lewy body dementia, amyotrophic lateral sclerosis, progressive supranuclear palsy, stroke, atherosclerosis, emphysema, stroke, atherosclerosis, emphysema, and a cancer. The examiner notes that the knowledge and level of skill in this art would not permit one skilled in this art to assert a preventive therapeutic mode of administration and the skilled artisan could not immediately envisage the invention claimed. Applicant claims a method for preventing diseases or other conditions where free radicals and/or oxidative stress contribute to the pathogenesis, comprising: administering to mammal in need of such treatment an amount of a composition ..... effective for the prevention of said disease or condition, which is not generally known to exist in this art; additionally, the disclosure is silent with regard to that which makes up and identifies the claimed method for preventing the said disease, which is seen to be lacking a clear description via art recognized procedural and methodological steps. In addition, the prevention of such disease which includes Parkinson's Disease, Lewy body dementia, amyotrophic lateral

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sclerosis, progressive supranuclear palsy, stroke, atherosclerosis, emphysema, stroke, atherosclerosis, emphysema, and a cancer does not have a single recognized cause. In fact, the aforementioned diseases, are recognized as having many contributing factors, ranging from hereditary considerations, to lifestyles choices such as the diet and maintenance of bodily healthiness which includes (1) high blood pressure (2) high cholesterol (3) cigarette smoking (4) diabetes mellitus and (5) family history of diseases such as cancer, heart disease or stroke. These are only a few of the factors that promote these diseases in people. For example, it is not known yet exactly what causes Alzheimer's disease. Researchers are learning about what happens to the brain as we grow older, what happens to brain cells in Alzheimer's disease, genes associated with Alzheimer's, and many other factors that may be important. Most researchers agree that the cause may be a complex set of factors. Similarly, the exact cause of parkinson's disease is not known. Applicant has not provided a description as how any cause (like the aforementioned) can be prevented, much less a description of how the said disease can be prevented. Furthermore, Applicant has not provided any clear description via art recognized procedural and methodological steps. Moreover, Applicant has not provided an adequate representation of the mode of treatment of said diseases to provide a full, clear and precise indication that applicant is in possession of the members of the methodological and procedural steps which would enable the skilled artisan to practice this invention of prevention of said diseases.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pappolla (WO 99/42102) in view of Shapiro (WO 92/14456).

In claim 1, applicant claims "A composition useful for the treatment of diseases or other conditions where free radicals and/or oxidative stress contribute to the pathogenesis comprising an effective amount of a mixture of indole-3-propionic acid and chitosan whereby the mixture is prepared by mixing indole-3-propionic acid and chitosan in water to form a solution and filtering and drying the solution."

Pappolla discloses that the compound, indole-3-propionic acid can be used to treat diseases or other conditions where free radicals and/or oxidative stress play a role, by administering an effective amount of an indole-3-propionic acid or a salt or ester thereof (see abstract). Pappolla also discloses that the said diseases or condition include Parkinson's Disease, Lewy body dementia, amyotrophic lateral sclerosis, progressive supranuclear palsy, stroke, atherosclerosis, emphysema and cancer (see claims 17-19, pages 21 and 22). Furthermore, Pappolla discloses that indole-3-propionic acid can be used to treat diseases or conditions that also include fibrillogenic disease such as Alzheimer's and prion-related encephalopathy (see claims 9-12, page 21).

Shapiro discloses that non-absorbable polyamine agents and amine-related agents such as chitosan can be used to treat symptoms of disorders relating to neurological disease including Alzheimer's and Parkinson's diseases (see abstract).

The difference between applicant's claimed composition and the composition disclosed by Pappolla is that the applicant also uses chitosan in his composition in addition to the same compound (indole-3-propionic acid) used by Pappolla.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Pappolla and Shapiro, to prepare a composition comprising a combination of indole-3-propionic acid and chitosan to treat diseases or other conditions where free radicals and/or oxidative stress play a role such as the neurological diseases, Alzheimer's and Parkinson's diseases, since the combination of compounds that are used to treat the same diseases or condition is well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated in view of Pappolla and Shapiro, to prepare a composition comprising a combination of indole-3-propionic acid and chitosan, to treat diseases or other conditions where free radicals and/or oxidative stress play a role such as the neurological diseases, Alzheimer's and Parkinson's diseases, because a skilled artisan would reasonably be expected to prepare a composition comprising a combination of the compounds taught by Pappolla and Shiparo, to treat said diseases or conditions based on type and/or severity of the disease or condition.

In claim 2, applicant claims "A method for treating diseases or other conditions where free radicals and/or oxidative stress contribute to the pathogenesis, comprising: administering to a mammal in need of such treatment an amount of a composition of claim 1 effective for the treatment of said disease or condition. Claims 3-5 are drawn to a method of claim 2 wherein the

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administration include systemic, oral, topical and inhalation and the diseases includes Parkinson's disease and Alzheimer's. Claim 14 is drawn to a method of claim 2, wherein the disease or condition is aging of the skin.

Pappolla discloses a method of treating diseases or other conditions where free radicals and/or oxidative stress play a role, by administering an effective amount of an indole-3-propionic acid or a salt or ester thereof to a human subject (see abstract). Pappolla's method of treatment include the diseases or condition include Parkinson's Disease, Lewy body dementia, amyotrophic lateral sclerosis, progressive supranuclear palsy, stroke, atherosclerosis, emphysema and cancer (see claims 17-19, pages 21 and 22). Furthermore, Pappolla discloses that indole-3-propionic acid can be used to treat diseases or conditions that also include fibrillogenic disease such as Alzheimer's and prion-related encephalopathy (see claims 9-12, page 21).

Shapiro discloses that non-absorbable polyamine agents and amine-related agents such as chitosan can be used to treat symptoms of disorders relating to neurological disease including Alzheimer's and Parkinson's diseases (see abstract).

The difference between applicant's claimed method and the method disclosed by Pappolla is that the applicant also uses chitosan in his composition in addition to the same compound (indole-3-propionic acid) used by Pappolla.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Pappolla and Shapiro, to use the method of Pappolla to treat diseases or other conditions where free radicals and/or oxidative stress play a role such as the neurological diseases, Alzheimer's and Parkinson's diseases with a composition comprising a combination of indole-3-propionic acid and chitosan, since the combination of compounds that



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are used to treat the same diseases or condition is well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated in view of Pappolla and Shapiro, to use the method of Pappolla to treat diseases or other conditions where free radicals and/or oxidative stress play a role such as the neurological diseases, Alzheimer's and Parkinson's diseases with a composition comprising a combination of indole-3-propionic acid and chitosan, because a skilled artisan would reasonably be expected to prepare a composition comprising a combination of the compounds taught by Pappolla and Shiparo, to treat said diseases or conditions based on type and/or severity of the disease or condition. It should be noted that skin aging which include wrinkles of the skin; dry skin and discolorations, with loss of elasticity and flexibility is also be associated with diseases such as atherosclerosis, cancer, diabetes, stroke and asthma, and consequently such a treatment of these diseases as claimed by applicant also encompasses a treatment of aging skin.

In claim 6, applicant claims "A method of treating a fibrillogenic disease in a mammal comprising: administering an amount of a composition of claim 1 effective to prevent or reverse fibrillogenesis in a mammal." Claim 7, is drawn to the method of claim 6, wherein the fibrillogenic disease is a prion-related encephalopathy.

Pappolla discloses a method of treating diseases or other conditions where free radicals and/or oxidative stress play a role, by administering an effective amount of an indole-3-propionic acid or a salt or ester thereof to a human subject (see abstract). Pappolla's method of treatment

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include the diseases or condition include Parkinson's Disease, Lewy body dementia, amyotrophic lateral sclerosis, progressive supranuclear palsy, stroke, atherosclerosis, emphysema and cancer (see claims 17-19, pages 21 and 22). Furthermore, Pappolla discloses that indole-3-propionic acid can be used to treat diseases or conditions that also include fibrillogenic disease such as Alzheimer's and prion-related encephalopathy (see claims 9-12, page 21). Pappolla also discloses that treatment with indole-3-propionic acid is effective in preventing or reversing fibrillogenesis in a human (see abstract).

Shapiro discloses that non-absorbable polyamine agents and amine-related agents such as chitosan can be used to treat symptoms of disorders relating to neurological disease including the fibrillogenic disease, Alzheimer's (see abstract).

The difference between applicant's claimed method and the method disclosed by Pappolla is that the applicant also uses chitosan in his composition in addition to the same compound (indole-3-propionic acid) used by Pappolla.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Pappolla and Shapiro, to use the method of Pappolla to treat diseases or conditions that also include fibrillogenic disease such as Alzheimer's and prion-related encephalopathy with a composition comprising a combination of indole-3-propionic acid and chitosan, since the combination of compounds that are used to treat the same diseases or condition is well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated in view of Pappolla and Shapiro, to use the method of Pappolla to treat diseases or conditions that also include fibrillogenic disease such as Alzheimer's and prion-related encephalopathy with a composition comprising a combination of indole-3-propionic acid and chitosan, because a skilled artisan would reasonably be expected to prepare a composition comprising a combination of the compounds taught by Pappolla and Shapiro, to treat said diseases or conditions based on type and/or severity of the disease or condition.

In claim 8, applicant claims "A method of decreasing oxidation in a biological sample comprising: contacting the biological sample with an effective amount of the composition of claim 1. Claim 9 is drawn to the method according to claim 8, wherein the biological sample is a cell.

Pappolla discloses a method of decreasing oxidation in a biological sample comprising: contacting the biological sample, which also includes a cell, with an effective amount of an indole-3-propionic acid or a salt or ester thereof (see claims 13 and 14). Pappolla also discloses that indole-3-propionic acid prevents the cytotoxic effects of amyloid beta protein on cells (see abstract). Furthermore, Pappolla discloses that cytotoxic effects of the said amyloid beta protein occurs in neuronal cells of human subjects afflicted with fibrillogenic diseases, such as Alzheimer's disease (see page 9, lines 29-33). This suggests that decreasing the oxidation in biological cells of human subjects afflicted with fibrillogenic diseases, such as Alzheimer's disease contributes to the treatment of fibrillogenic diseases, such as Alzheimer's disease.

Shapiro discloses that non-absorbable polyamine agents and amine-related agents such as chitosan can be used to treat symptoms of disorders relating to neurological disease including the fibrillogenic disease, Alzheimer's (see abstract).

The difference between applicant's claimed method and the method disclosed by Pappolla is that the applicant also uses chitosan in his composition in addition to the same compound (indole-3-propionic acid) used by Pappolla.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Pappolla and Shapiro, to use the method of Pappolla to treat contacting the biological sample, such as a cell, with a composition comprising a combination of indole-3-propionic acid and chitosan, since the combination of compounds that are used to treat the same diseases or condition is well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated in view of Pappolla and Shapiro, to use the method of Pappolla to treat contacting the biological sample, such as a cell, with a composition comprising a combination of indole-3-propionic acid and chitosan, because a skilled artisan would reasonably be expected to prepare a composition comprising a combination of the compounds taught by Pappolla and Shapiro, to treat said diseases or conditions based on type and/or severity of the disease or condition.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652.

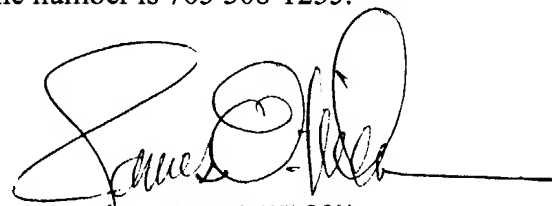
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The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

September 24, 2004.



JAMES O. WILSON  
SUPERVISORY PATENT EXAMINER  
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